IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, et al., ex rel., CHARLES STRUNCK, et al., Plaintiffs, v. MALLINCKRODT ARD LLC (f/k/a Mallinckrodt ARD, Inc.; f/k/a Questcor Pharmaceuticals, Inc.), Defendant.	:	Civil Action No. 12-CV-0175

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS THE UNITED STATES' COMPLAINT IN INTERVENTION AND TO STRIKE PORTIONS THEREOF

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Pursuant to Federal Rules of Civil Procedure 12(b)(6) and 12(f), Defendant Mallinckrodt ARD LLC, formerly known as Questcor Pharmaceuticals, Inc. ("Questcor"),[1] respectfully submits this memorandum of law in support of its motion to dismiss the United States' Complaint in Intervention (the "Complaint" or "Compl.") for failure to state a claim and to strike Paragraph 199 and footnote 5 therein. For the reasons set forth below, the motion should be granted.

PRELIMINARY STATEMENT

The False Claims Act ("FCA") exists to redress fraudulent activity that attempts to, or actually does, cause economic loss to the United States. Because FCA liability attaches only when a person or company knowingly perpetrates fraud on the government, there can be no FCA liability for conduct that complies with regulatory guidance. Yet that outcome is precisely what the United States seeks to achieve through this action. The United States contends that, between 2010 and 2014, Questcor caused the submission of false Medicare claims for Questcor's specialty drug Acthar® Gel (repository corticotropin injection) ("Acthar") solely because Questcor made donations to the Chronic Disease Fund ("CDF"), a charitable foundation that subsidized patient copays for financially needy patients.

The United States does not allege that Acthar was not a covered drug for purposes of Medicare reimbursement. There is no allegation that claims were submitted for Acthar

[1] On August 14, 2014, Mallinckrodt plc effectuated the acquisition of Questcor, with Questcor surviving the merger as a wholly owned indirect subsidiary of Mallinckrodt plc. (Compl. ¶¶ 15, 16.) Today, Questcor is known as Mallinckrodt ARD LLC and has its principal place of business in Bedminster, New Jersey. (*Id.* ¶ 14.) Notwithstanding that substantially all the conduct alleged in the Complaint occurred prior to the acquisition (*id.* ¶ 2), at a time when the entity was known as Questcor, the United States refers to the defendant as "Mallinckrodt." For both clarity and accuracy, the entity at issue will be referred to herein as Questcor.

prescriptions that were not actually disbursed to Medicare beneficiaries. There is no allegation that the prescribed Acthar was not medically necessary for any Medicare beneficiary or that the Medicare beneficiaries who received Acthar did not benefit from the drug. Instead, the United States alleges that *all* claims for Acthar involving copay subsidies provided through CDF to financially needy Medicare beneficiaries were false because Questcor's conduct in making charitable donations to CDF constituted a violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b). In effect, the United States contends that covered Medicare patients who were appropriately prescribed Acthar were required to choose between personally paying copays they could not afford, which are determined under a standard Medicare formula, or foregoing properly prescribed and medically necessary medication. As to Medicare beneficiaries, the United States' position is disturbing; as to Questcor, it is legally baseless.

During the period at issue in the Complaint, the Department of Health and Human Services Office of Inspector General ("OIG") expressly *endorsed* patient assistance programs for Medicare Part D enrollees, including pharmaceutical manufacturer funding of such programs, and specifically *approved* CDF's patient assistance programs at issue here. Questcor's donations to CDF were consistent with both the formal guidance issued by the OIG in 2005 and the OIG's subsequent advisory opinions to charitable organizations that offered these patient assistance programs, including CDF. In light of the OIG's explicit endorsement of this type of charitable contribution arrangement, Questcor's conduct did not, and could not, violate the AKS. Moreover, in 2014, the OIG revised its guidance and modified its advisory opinions, demonstrating that its initial guidance was, at best, ambiguous, thereby rendering the United States unable as a matter of law to plausibly allege that Questcor acted knowingly within the

meaning of either the AKS or the FCA. The United States' claims against Questcor thus cannot survive scrutiny under Rule 12(b)(6) and should be dismissed.

Seeking to buttress its legally deficient claims against Questcor, the United States alleges that "it has pursued matters against drug companies like [Questcor] for conduct like that alleged here" and cites recent settlements with other companies. (Compl. ¶ 199 & n.5.) That the United States has entered into civil settlements with other pharmaceutical companies relating to other drugs is patently irrelevant to the United States' claims against Questcor, and the prejudicial allegations as to these settled matters should be stricken pursuant to Rule 12(f). But far from supporting the United States' claims against Questcor, the fact that the United States has entered into civil settlements with respect to purported criminal violations of the AKS serves only to demonstrate the uncertainty surrounding the OIG's initial guidance.

The United States' claims should be dismissed in their entirety with prejudice.

RELEVANT BACKGROUND[2]

A. The OIG's 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees

The OIG has long supported patient assistance programs like those provided by CDF: "Long-standing OIG guidance makes clear that industry stakeholders can effectively contribute to the health care safety net for financially needy Medicare beneficiaries by contributing to independent, *bona fide* charitable assistance programs. Under a properly structured program,

[2] Portions of this background are drawn from the factual allegations of the Complaint. Although the Court must, on this motion only, accept as true well-pleaded factual allegations, it need not accept as true "unsupported conclusions and unwarranted inferences," *Doug Grant, Inc. v. Greate Bay Casino Corp.*, 232 F.3d 173, 183-84 (3d Cir. 2000) (citations omitted), or the United States' numerous "bald assertions" and "legal conclusions," *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (citations omitted). Questcor does not admit the truth or accuracy of any averment in the Complaint.

such donations should raise few, if any, concerns about improper beneficiary inducements." OIG Adv. Op. No. 06-10 at 6 (Sept. 14, 2006).[3] In its 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (the "2005 SAB"), the OIG expressly endorsed such programs, including pharmaceutical manufacturer funding of them. It said:

- "OIG is mindful of the importance of ensuring that financially needy beneficiaries who enroll in Part D receive medically necessary drugs, and **OIG supports efforts of charitable organizations and others to assist financially needy beneficiaries**, as long as the assistance does not run afoul of the Federal anti-kickback statute or other laws."

- "[I]n the circumstances described in this Bulletin, cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, **even if the charities receive manufacturer contributions**."

- "[W]e believe **lawful avenues exist for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs**."

70 Fed. Reg. 70,623, 70,624 (Nov. 22, 2005) (emphases added).[4] Shortly after the OIG issued the 2005 SAB, members of the Senate Finance Committee called on drug companies to continue patient assistance programs and emphasized that the Medicare Part D benefit "does not and should not prevent them from continuing to offer patient assistance programs to Medicare beneficiaries who enroll in Part D." *Senators Call on Drug Company Leaders to Continue Drug Assistance Programs*, U.S. Sen. Comm. on Fin. (May 11, 2006),

[3] A copy of OIG Advisory Opinion No. 06-10 is attached as Exhibit A. As alleged in the Complaint, this Advisory Opinion was issued by the OIG to CDF in 2006 when the OIG approved CDF's patient assistance programs. (Compl. ¶ 178.)

[4] A copy of the 2005 SAB is attached as Exhibit B. The OIG is authorized by statute and regulation to issue guidance and advisory opinions regarding application of the AKS. 42 U.S.C. § 1320a-7d(b); 42 C.F.R. pt. 1008. Although the United States incorporates by reference and quotes from the 2005 SAB in the Complaint (*see* Compl. ¶¶ 173-177), it does not include any of this language.

https://www.finance.senate.gov/release/senators-call-ondrug-company-leaders-to-continue-drug-assistance-programs (statement of Sen. Chuck Grassley) (Ex. C). Senator Grassley stated: "Out-of-pocket costs for hyper-expensive drugs can be an insurmountable barrier for many beneficiaries even with the new Medicare benefit." *Id.* Senator Max Baucus stated: "There's absolutely no reason drug companies can't keep serving people in need." *Id.* (statement of Sen. Max Caucus). And Senator Orrin Hatch reported that "[d]rug companies now have the green light to complement the new Medicare program with their assistance programs," and he encouraged "drug companies" to "continue giving generously to help our seniors." *Id.* (statement of Sen. Orrin Hatch).

Consistent with the 2005 SAB, between 2005 and 2014, the OIG issued at least eight advisory opinions approving programs offered by nonprofit, tax-exempt charitable organizations that provide financial support to financially needy patients, including programs directed at Medicare Part D beneficiaries, programs funded in large part by pharmaceutical manufacturers, programs focused on particular diseases or particular medical conditions, and programs available only to patients using a specialty therapeutic. *See* OIG Adv. Op. Nos. 06-04 (Apr. 20, 2006), 06-09 (Aug. 18, 2006), 06-10 (Sept. 14, 2006), 07-06 (July 23, 2007), 07-11 (Sept. 28, 2007), 07-18 (Dec. 19, 2007), 09-04 (May 11, 2009), 11-05 (May 13, 2011); *see also* OIG Adv. Op. No. 04-15 (Oct. 29, 2004).[5] Particularly relevant here, several OIG advisory opinions – including the

[5] Copies of these Advisory Opinions are attached as Exhibits A, and D through K. They are subject to judicial notice and are properly considered in ruling on a motion to dismiss. *See U.S. ex rel. Streck v. Allergan, Inc.*, 746 F. App'x 101, 108-09 (3d Cir. 2018) (taking judicial notice of and considering administrative guidance in affirming dismissal of motion to dismiss); *United States v. Medtronic, Inc.*, No. 5:2015-cv-06264, 2017 WL 2653568, at *4 n.2 (E.D. Pa. June 19, 2017) ("The court recognizes that such administrative guidance does not constitute binding law, but finds it persuasive in deciding whether the conduct alleged falls under the AKS's umbrella of illegal remuneration."). Moreover, the Complaint *(cont'd)*

OIG's approval of CDF's patient assistance program – approved programs where, in "rare circumstances," "there may be only one drug covered by Part D for the disease in a particular category or only one pharmaceutical manufacturer (including its affiliates) that makes all of the Part D covered drugs for the diseases in a particular disease category." OIG Adv. Op. Nos. 06-10 at 5 n.7, 06-04 at 5 n.5, 07-06 at 5 n.4; *see also* OIG Adv. Op. Nos. 07-11 at 4 n.1, 07-18 at 6 n.5.

B. The OIG's 2014 Supplemental Special Advisory Bulletin Regarding Independent Charity Patient Assistance Programs

In 2014, nine years after the issuance of its original guidance and following several subsequent advisory opinions confirming that original guidance, the OIG elected to revise its guidance regarding patient assistance programs "based on experience we have gained" since issuing the 2005 SAB. 79 Fed. Reg. 31,120, 31,120 (May 30, 2014). Toward that end, on May 30, 2014, the OIG published a Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs (the "2014 SAB") in which the OIG provided new guidance concerning independent charity patient assistance programs.[6]

Among other things, the OIG expanded the definition of the type of disease funds that would cause the OIG concern, which since 2005 had been limited to funds "defined by reference to specific symptoms, severity of symptoms, or the method of administration of the drugs," to more expansively include "funds defined by reference to the stages of a particular disease, the type of drug treatment, and any other ways of narrowing the definition of widely recognized

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incorporates by reference Advisory Opinion No. 06-10, which was issued to CDF in 2006, providing a website address at which the opinion can be found. (Compl. ¶ 178.)

[6] A copy of the 2014 SAB, which is incorporated by reference in the Complaint at footnote 3, is attached as Exhibit L.

disease states." *Id.* at 31,121. As to single drug funds, the OIG recognized that its earlier SAB had noted that "the fact that a disease fund includes only one drug or drugs made by one manufacturer would not, standing alone, be determinative of an anti-kickback statute violation," but added that "a disease fund that covers only a single product, or the products made or marketed by only a single manufacturer that is a major donor to the fund, will be subject to scrutiny." *Id.* at 31,122. The 2014 SAB further stated that "[w]hen determining whether an anti-kickback violation occurred, we would consider, among other factors, whether the disease fund in question appears to be narrowly defined in a manner that favors any of the fund's donors." *Id.*

Following issuance of the 2014 SAB, the OIG changed six of its prior advisory opinions to specifically address its newly revised approach to patient assistance programs and required the charities that initially had requested guidance to make significant, substantive changes to their programs in order to maintain their favorable advisory opinions. *See* Not. of Mod. of OIG Adv. Op. Nos. 06-04 (Dec. 23, 2015), 06-10 (Oct. 26, 2015), 07-06 (Dec. 21, 2015), 07-11 (Nov. 30, 2015), 07-18 (Oct. 26, 2015), 11-05 (Dec. 21, 2015).[7] In October 2015, the OIG issued a modification to Advisory Opinion No. 06-10 (through which it had approved CDF's patient assistance program), noting that it sent CDF a letter highlighting its areas of concern, explaining that certain aspects of CDF's patient assistance program would have to be modified in order for CDF to retain its favorable advisory opinion, and proposing that certifications be made by CDF to address these points. *See* Not. of Mod. Of OIG Adv. Op. No. 06-10. The modification specifically noted that the OIG's initial advisory opinion to CDF had "***approved certain features***

[7] Copies of the Notices of Modification of OIG Advisory Opinions are attached as Exhibits M through R. Notwithstanding that the 2014 SAB so changed the regulatory landscape that the OIG had to modify the advisory opinions it had issued in accordance with its 2005 guidance, the United States references the 2014 SAB only in a footnote, suggesting that it merely "reiterate[d]" concepts from the 2005 SAB. (Compl. ¶ 174 n.3.)

that ***we have since determined are problematic***." *See id.* at 2 (emphases added); *see also* Not. of Mod. of OIG Adv. Op. Nos. 06-04 (Dec. 23, 2015), 07-06 (Dec. 21, 2015), 07-11 (Nov. 30, 2015), 07-18 (Oct. 26, 2015). In response to the OIG's concerns, CDF agreed that, going forward, it would not (1) "define its disease funds by reference to . . . stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states," (2) "maintain any disease fund that provides copayment assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates," or (3) "limit its assistance to high-cost or specialty drugs." Mod. of OIG Adv. Op. No. 06-10 at 2. Based on these modifications to the program, CDF maintained its favorable advisory opinion. *Id.* at 3 ("the advisory opinion continues in full force and effect *in modified form*" (emphasis added)).[8]

C. The United States' Allegations Against Questcor

Acthar is an adrenocorticotrophic hormone analogue that has been approved by the U.S. Food and Drug Administration ("FDA") for 19 indications across 5 therapeutic areas, including for the treatment of acute exacerbations of multiple sclerosis in adults, for treatment during an exacerbation or as maintenance therapy in selected cases of lupus, as adjunctive therapy for short-term administration in rheumatoid arthritis, and to treat a rare seizure disorder afflicting children called infantile spasms. (*See* Compl. ¶¶ 58-59, 61-64.)[9] With respect to exacerbations

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[8] The United States selectively cites the OIG's 2006 Advisory Opinion to CDF (Compl. ¶ 178), failing to mention that the OIG modified the opinion in 2015 following issuance of the 2014 SAB and after requiring that CDF make changes to the program that the OIG had approved in 2006.

[9] The United States tacitly questions Acthar's efficacy (*see* Compl. ¶¶ 59-60), but necessarily concedes that the FDA has approved Acthar for multiple uses and that health care providers have continually prescribed Acthar for their patients. (*E.g. id.* ¶¶ 60-64.) Moreover, FDA *(cont'd)*

of multiple sclerosis, lupus and rheumatoid arthritis, Acthar is a unique, later-line treatment, prescribed by skilled healthcare providers to a small subset of patients who do not respond to or cannot tolerate more widely prescribed steroids, which typically are a first-line treatment. For this reason, Acthar is a last resort alternative treatment option.

Questcor acquired worldwide rights to sell and manufacture Acthar in July 2001. (*Id.* ¶ 65.) During the period July 2001 through 2006, "the majority of Acthar sales came from referrals for [infantile spasm] patients by pediatric neurologists." (*Id.* ¶ 67.) Questcor therefore decided to position Acthar as a preferred therapy for infantile spasms and pivot away from marketing Acthar for multiple sclerosis and other more common diseases. (*Id.* ¶ 68.) Because infantile spasms is a rare disorder, Questcor adopted an "orphan pricing strategy" (*see id.*) – a standard pricing practice for drugs with small patient populations.[10]

According to the Complaint, not long after Questcor "terminated its [multiple sclerosis] sales force and dedicated remaining account representatives to work with [infantile spasm] prescribers" (*id.* ¶ 71), Questcor "re-established a pilot [multiple sclerosis] sales force in 2008 to try to generate Acthar [multiple sclerosis] referrals at the new price" (*id.* ¶ 80). The Complaint alleges that Questcor "realized subsidizing patient copay obligations could overcome some doctor and patient cost concerns (*id.* ¶ 83) and that Questcor "knew that it was illegal to

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conducted a full review and modernization of Acthar's label in 2010, at which time it added infantile spasms to the list of approved indications for the drug. (*See id.* ¶ 64.)

[10] The United States attempts to make much about this orphan pricing strategy and the price of Acthar over time. (*See* Compl. ¶¶ 3, 68, 69, 73, 79, 159.) But the Complaint itself confirms that the market for Acthar was constrained: prior to implementation of orphan pricing strategy, multiple sclerosis referrals nationwide were 250 vials per month (*id.* ¶ 72); during most of the relevant time period, there were fewer than 1000 vials prescribed nationwide per month (*id.* ¶ 156). In any event, these pricing allegations have no bearing on the propriety of Questcor's conduct in making donations to CDF.

subsidize Medicare copays directly" (*id.* ¶ 84). The Complaint further alleges that Questcor therefore "sought to accomplish the same result through a 'copay assistance fund' that it designed, created, and used as a money conduit to pay patient copay subsidies for Acthar (but no other drug)." (*Id.*)

The facts alleged by the United States demonstrate that, far from being a mere "conduit" for Questcor, CDF was a *bona fide*, independent charity that Questcor supported in accordance with OIG guidance issued during the relevant time frame. (*Id.* ¶¶ 88-127.) In particular, the Complaint alleges that *CDF* – not Questcor – made the determination as to whether the proposed patient assistance funds at issue were appropriate. (*Id.* ¶ 88 (CDF's President advised Questor's consultant that the proposed fund "comfortably" could be defined "as specific to MS exacerbation"); *id.* ¶¶ 108-112 (describing coordination with CDF regarding copay fund for lupus exacerbation); *id.* ¶¶ 124-125 (describing coordination with CDF regarding copay fund for rheumatoid arthritis exacerbation).) In fact, as alleged in the Complaint, when Questcor approached CDF about opening a rheumatoid arthritis exacerbation fund, CDF responded that it "needed to confer with its own counsel before proceeding further." (*Id.* ¶ 125.)

Although the United States alleges that Questcor directed Medicare patients to CDF if they needed copay assistance and that Questcor's donations were used almost exclusively to subsidize copays for Acthar (*see id.* ¶¶ 137-153), these allegations do not bear on CDF's independence or the *bona fide* nature of the charitable services CDF provided to Medicare Part D beneficiaries. Rather, the United States' criticisms arise from the fact that CDF maintained single drug funds that benefited almost exclusively Acthar patients. (*See id.* ¶¶ 146-153.)[11] But,

[11] CDF and Questcor reasonably believed that Acthar was unique and fell within the purview of the OIG paradigm for "one Specialty Therapeutic to treat a particular Funded Disease." OIG Adv. Op. No. 06-10 at 5 n.7. Acthar was a drug of last resort, meaning that it was only used *(cont'd)*

as noted above, the OIG recognized in its 2005 SAB and in multiple advisory opinions thereafter – including the opinion it issued to CDF in 2006 – that single drug funds were not inherently improper. In so recognizing, the OIG necessarily understood that charities (including CDF) would establish charitable funds (like the multiple sclerosis exacerbation, lupus exacerbation and rheumatoid arthritis exacerbation funds established by CDF) funded by drug manufacturers (like Questcor) that supported a single, high-cost drug (like Acthar).

The OIG's approval of such funds continued until 2014 when the OIG changed its guidance and expressed its new view that funds should not be narrowly drawn and that single drug funds would be subject to scrutiny. *Compare* 2005 SAB *with* 2014 SAB. Confirming that this was a sea change in the OIG's position, the OIG modified multiple advisory opinions approving charitable programs only after the charities agreed to changed behavior consistent with the OIG's revised guidance. *See* Not. of Mod. of OIG Adv. Op. Nos. 06-04, 06-10, 07-06, 07-11, 07-18, 11-05. In doing so, the OIG explicitly stated that it had previously approved certain features in the charitable programs that it had "since determined are problematic." *See* Not. of Mod. of OIG Adv. Op. Nos. 06-04, 06-10, 07-06, 07-11, 07-18. Questcor's purported improper conduct ceased at or about the time of the OIG's revised guidance and modified advisory opinions. (*See* Compl. ¶ 2 (defining relevant time period as ending in 2014).)

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to treat MS exacerbations if the patient had tried less costly steroids and either could not tolerate that medication or obtain the desired relief. As a result, only a small patient population qualified for treatment with Acthar. (*See* Compl. ¶ 156.) In addition, treatment of MS exacerbations required prompt administration of Acthar, which was greatly facilitated by the single drug fund opened and administered by CDF.

ARGUMENT

I. LEGAL STANDARD

Under Federal Rule of Civil Procedure 8, to survive dismissal, a complaint must "show" – not merely assert – a plaintiff's entitlement to relief. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 n.3 (2007). In particular, factual allegations must be "enough to raise a right to relief above the speculative level" and the claims asserted must be "plausible on [their] face." *Id.* at 555, 570; *see also Ashcroft v. Iqbal*, 556 U.S. 662, 680 (2009) (bare and conclusory assertions do not suffice to "'nudge[] claims' . . . 'across the line from conceivable to plausible'") (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Even "well-pleaded factual allegations" are insufficient to state a claim for relief if they "do not permit the court to infer more than the mere possibility of misconduct." *Id.* at 679; *see also U.S. ex rel. Pilecki-Simko v. Chubb Inst.*, 443 F. App'x 754, 761 (3d Cir. 2011) (affirming dismissal of FCA claims where relator failed to allege sufficient facts to allow the court to draw the reasonable inference that the defendant was liable for the misconduct alleged).

Moreover, because such claims sound in fraud, "plaintiffs must plead FCA claims with particularity in accordance with Rule 9(b)." *Pilecki-Simko*, 443 F. App'x at 758 n.12. To satisfy Rule 9(b) in the FCA context, a plaintiff must allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *U.S. ex rel. Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 156 (3d Cir. 2014) (citation omitted).

II. THE COMPLAINT FAILS TO STATE A CLAIM FOR VIOLATION OF THE FALSE CLAIMS ACT.

The United States' claims under Sections 3729(a)(1)(A) and 3729(a)(1)(B) of the FCA are based solely on the premise that all claims for Acthar involving copay subsidies provided by CDF to Medicare beneficiaries were false because Questcor's charitable donations to CDF violated the AKS. (*See* Compl. ¶¶ 223-230.) To state a claim for violation of Section 3729(a)(1)(A), a plaintiff must show: "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 182 (3d Cir. 2001). To state a claim for violation of Section 3729(a)(1)(B), a plaintiff must allege that the defendant knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims. 31 U.S.C. § 3729(a)(1)(B).

"[C]laims for payment made pursuant to illegal kickbacks are false under the False Claims Act." *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 95 (3d Cir. 2018) (citations omitted). To plausibly allege a violation of the AKS, however, a plaintiff must allege facts demonstrating that the defendant "***knowingly and willfully***" offered or paid "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" to induce any person "(B) to purchase, lease, order, or arrange for . . . any good, facility, service, or item, for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2) (emphasis added). Moreover, to allege knowing conduct within the meaning of the FCA, a plaintiff must plausibly allege that the defendant had "***actual knowledge*** that the alleged false claims were fraudulent, ***deliberate ignorance*** as to the claims' fraudulent nature, or ***reckless disregard*** of the claims' truth or

falsity." *Medtronic*, 2017 WL 2653568, at *5 (emphases added); *see also* 31 U.S.C. § 3729(b)(1) (defining "knowledge"). Because Questcor's alleged conduct was consistent with OIG guidance during the relevant time frame, the facts alleged do not plausibly state an AKS violation and they do not plausibly allege that Questcor acted knowingly within the meaning of either the AKS or the FCA. The United States therefore has not stated a claim against Questcor.

A. The Complaint Does Not Plausibly Allege a Violation of the Anti-Kickback Statute.

Because the United States does not allege that Questcor directly subsidized copays of Medicare beneficiaries, the legal sufficiency of the United States' claims hinges on whether Questcor's financial support of CDF, which subsidized the copays of Medicare Part D beneficiaries in accordance with an Advisory Opinion issued by the OIG in 2006, constituted a violation of the AKS. As discussed above, the OIG issued industry-wide guidance in 2005 in which it re-affirmed the need for independent charities to serve as a safety net for financially needy Medicare patients; the OIG provided guidance as to how such charities should operate; and the OIG recognized the potential for funds to be focused on specialty drugs, including in rare circumstances, single drug funds. *See* 2005 SAB, 70 Fed. Reg. at 70,627.

Although the United States recasts the purpose of the 2005 SAB as a "warn[ing]" to "drug companies . . . against using foundations as conduits" to pay Medicare copays (Compl. ¶ 172), the text of the 2005 SAB belies this assertion. In describing the purpose of the 2005 SAB, the OIG stated:

> We have been asked whether the anti-kickback statute will be implicated if pharmaceutical manufacturer [patient assistance programs] continue to offer assistance to financially needy Medicare beneficiaries who enroll in Part D by subsidizing their cost-sharing obligations for covered Part D drugs. For the reasons set forth below and consistent with extant OIG guidance, we conclude that pharmaceutical manufacturer [patient assistance programs] that subsidize Part D cost-sharing amounts present heightened risks under the anti-kickback statute. **However, in the circumstances described in this Bulletin, cost-sharing**

> **subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions.** In addition, we believe other arrangements described in this Bulletin, if properly structured, may pose reduced risk. **Thus, we believe lawful avenues exist for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs.**

2005 SAB, 70 Fed. Reg. at 70,624 (emphases added). Thus, far from warning drug companies *not to* use foundations to pay Medicare copays, the 2005 SAB provided a roadmap as to how drug companies permissibly could support foundations "to ensure that all Part D beneficiaries can afford medically necessary drugs." *Id.* Following issuance of the 2005 SAB, members of the Senate Finance Committee called on drug companies to continue drug assistance programs with Senator Hatch encouraging them to "giv[e] generously." (Ex. C.)

Thereafter, the OIG issued advisory opinions to a number of charitable foundations, including CDF, approving programs that provided copay assistance to Medicare Part D beneficiaries. *See*, *e.g.*, OIG Adv. Op. Nos. 06-04, 06-09, 06-10, 07-06, 07-11, 07-18, 09-04, 11-05. As relevant here, in Advisory Opinion No. 06-10, the OIG approved CDF's specialty therapeutics program with respect to "financially needy Medicare beneficiaries, including beneficiaries enrolled in a Part D plan." OIG Adv. Op. No. 06-10 at 2. The Advisory Opinion recognized that specialty therapeutics "are costly medications," that CDF's funding was provided by, among others, "manufacturers of the Specialty Therapeutics," and that "donors may earmark their contributions for the support of patients with a specific Funded Disease." *Id.* at 4-5. The Advisory Opinion further recognized that "[i]n rare circumstances . . . there may be only one Specialty Therapeutic to treat a particular Funded Disease." *Id.* at 5 n.7. Finally, the Advisory Opinion recognized that CDF "informs donors of the aggregate number of all applicants for assistance for particular Funded Diseases and the aggregate number of patients qualifying for assistance for particular Funded Diseases." *Id.* at 5. Based on the facts presented to it, the OIG

concluded: "In these circumstances, we do not believe that the contributions made by donors to [CDF] can reasonably be construed as payments to eligible beneficiaries of the Medicare program or to [CDF] to arrange for referrals." *Id.* at 8. The OIG noted that its conclusion was "consistent" with the 2005 SAB "in which the OIG made it clear that, in the circumstances described in the Bulletin, cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with donors should not raise anti-kickback concerns, even if the charities receive charitable contributions from those donors." *Id.* at 8 n.8.

The United States does not allege that CDF was not a *bona fide*, independent charity. Advisory Opinion No. 06-10 was issued to CDF in September 2006 – almost four years before Questcor started making donations to the organization. (*See* Compl. ¶¶ 155, 178.) Indeed, according to the United States, when Questcor decided to do business with CDF in the spring of 2010, it did so because it viewed CDF as the "WalMart" of the charitable foundation industry. (*Id.* ¶ 91.) The Complaint, moreover, is replete with allegations demonstrating that CDF operated independently from Questcor, including that CDF made the ultimate decision whether and how to create a fund, noting in one instance that "CDF needed to confer with its own counsel before proceeding further." (*Id.* ¶ 125; *see also id.* ¶ 88 (quoting email in which CDF's president determined the appropriateness of establishing MS exacerbation fund); *id.* ¶ 133 (acknowledging that CDF did not approve all Acthar patients for copay assistance); *id.* ¶ 153 (acknowledging that CDF has the ability independently to distribute Questcor donations to funds as CDF deemed appropriate).)

The United States also does not allege facts plausibly suggesting that Questcor controlled CDF. The Complaint does not allege that Questcor was a major or influential donor to CDF, that Questcor developed or advised on the eligibility criteria that CDF used to award copay grants,

that Questcor conditioned donations on CDF's acquiescence to a fund name, that Questcor conditioned donations on CDF's acquiescence to certain eligibility criteria, or that Questcor threatened to pull donations from CDF. Critically, it does not allege that Questcor demanded (or even asked) CDF not to cover steroids or other non-drug expenses.

With respect to reports from CDF, the Complaint alleges that Questcor received program reports "containing information about how many patients were enrolled in the fund, how much the fund had already paid out, and how much had been allocated to enrolled patients," along with "the percentage of patients approved to receive copay subsidies, the average copay amount paid by the fund, the total number of resulting drug 'dispenses' (broken out by new dispensers vs. refills), and the remaining fund balance" – the same type of information CDF told the OIG it would provide to donors. (*Compare* Compl. ¶ 147 *with* OIG Adv. Op. No. 06-10 at 5.) That "these reported metrics were specific to Acthar" (Compl. ¶ 148) is of no moment and certainly cannot serve as the basis for an AKS violation by Questcor. Those metrics were specific to Acthar because the CDF patient assistance funds at issue were single drug funds and, as a result, all metrics reported by CDF inherently and necessarily referenced the drug at issue. As the OIG's paradigm included the potential for one "Specialty Therapeutic to treat a particular Funded Disease," this was both known to and expressly approved by the OIG in 2006 when it issued Advisory Opinion No. 06-10. *See* OIG Adv. Op. No. 06-10 at 5 n.7.

To be sure, the OIG ultimately determined in 2014 that single drug funds would be subject to "scrutiny." 2014 SAB, 79 Fed. Reg. at 31,122. But nine years earlier, the OIG had advised the industry that "the fact that a disease category only includes one drug or manufacturer would not, standing alone, be determinative of an anti-kickback statute violation." 2005 SAB, 70 Fed. Reg. at 70,627 n.19. In 2005, the OIG further advised that "[s]uch a determination could

only be made on a case-by-case basis after examining all of the applicable facts and circumstances including the intent of the parties," noting "that it would be important for the [patient assistance] program to cover additional products or manufacturers as they become available." *Id.* Then, in 2006, when it approved CDF's specialty therapeutics program for Medicare beneficiaries, the OIG applied this guidance, stating: "In rare circumstances, where there may be only one Specialty Therapeutic to treat a particular Funded Disease or only one pharmaceutical manufacturer (including its affiliates) that makes all of the Specialty Therapeutics for the Funded Disease, Requestor will use its best efforts to cover additional products and manufacturers as they become available." OIG Adv. Op. 06-10 at 5 n.7.[12]

In short, the United States alleges facts that comport with both the general guidance the OIG provided to the industry in 2005 and the specific guidance the OIG provided to CDF in 2006 regarding the manner in which pharmaceutical manufacturers could lawfully contribute to charitable foundations without running afoul of the AKS. Although the OIG has since changed its position – and provided revised guidance and modified advisory opinions reflecting the change – that does not render the conduct that occurred prior to the OIG's changes unlawful. The United States simply does not allege a plausible violation of the AKS by Questcor. And, because the alleged AKS violations are the only basis on which the United States asserts that claims for Acthar were false, the United States also has failed to plausibly allege a "false or fraudulent" claim, 31 U.S.C. § 3729(a)(1)(A), or a "false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B). The Complaint should, therefore, be dismissed.

[12] The United States does not – and cannot – allege that other products became available during the relevant time frame to address the small patient population that could not tolerate or benefit from steroids.

B. The Complaint Does Not Plausibly Allege that Questcor Acted Knowingly.

The OIG's change in position in 2014 further confirms that the United States has not pled a viable violation of either the AKS or the FCA: the regulatory ambiguity between 2005 and 2014, at a minimum, precludes the United States from plausibly alleging, as it must, that Questcor acted "knowingly." As the Supreme Court has held, when the "statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one interpretation as a knowing or reckless violator." *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 n.20 (2007); *see also Streck*, 746 F. App'x at 106 (affirming dismissal of FCA claims where defendants proffered "a reasonable, but erroneous, interpretation of a statute"); *U.S. ex rel. Pritsker v. Sodexho, Inc.*, No. 03-6003, 2009 WL 579380, at *16 n.7 (E.D. Pa. Mar. 6, 2009) ("[A]n ambiguous regulatory interpretation that reasonably could be read to authorize Defendants' conduct precludes a finding that Defendants knowingly submitted a false claim."), *aff'd*, 364 F. App'x 787 (3d Cir. 2010); *U.S. ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 657 F. Supp. 2d 1039, 1057 (S.D. Iowa 2009) (citing to *Safeco* as to why defendant did not operate with reckless disregard under the FCA), *aff'd*, 316 F.3d 1186 (8th Cir. 2010); *U.S. ex rel. K & R Ltd. P'ship v. Mass. Hous. Fin. Agency*, 530 F.3d 980, 983 (D.C. Cir. 2008) (plaintiff never "explains why [the defendant's] interpretation of the mortgage notes was unreasonable, much less why its interpretation constituted reckless disregard . . . . [The plaintiff] points to nothing else 'that might have warned [the defendant] away from the view it took.'") (quoting *Safeco*, 551 U.S. at 70).[13]

[13] *See also United States v. Medica-Rents Co.*, Nos. 03-11297, 06-10393, 07-10414, 2008 WL 3876307, at *3 (5th Cir. Aug. 19, 2008) (refusing to impose FCA liability due to "substantial confusion created by contradictory instructions and guidance"); *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) (affirming summary judgment in favor of FCA defendant and stating that "differences in interpretation growing out of a disputed legal *(cont'd)*

As explained in *Streck*, "[b]asing a defense on a reasonable, but erroneous, interpretation of a statute includes three distinct inquiries: (1) whether the relevant statute was ambiguous; (2) whether a defendant's interpretation of that ambiguity was objectively unreasonable; and (3) whether a defendant was 'warned away' from that interpretation by available administrative and judicial guidance." 746 F. App'x at 106. Here, the OIG's 2005 industry-wide guidance was followed by at least eight OIG advisory opinions implementing that guidance. Then, in 2014, the OIG issued new guidance "based on experience we have gained in the intervening years." 2014 SAB, 79 Fed. Reg. at 31,120. In issuing the revised guidance, the OIG abandoned in key respects its 2005 guidance to the industry, establishing a marked shift in regulatory approach or, at a minimum, confirming ambiguity in its initial guidance. For example:

- The OIG's express requirement that patient assistance charities not maintain any disease fund that provides copayment assistance for only one drug or only drugs made or marketed by one manufacturer or its affiliates constituted a *complete departure* from the numerous advisory opinions expressly recognizing the potential for single drug/single donor funds. *Compare* 2014 SAB, 79 Fed. Reg. at 31,122, *with* OIG Adv. Op. 06-10 at 5 n.7, OIG Adv. Op. No. 06-04 at 5 n.5, OIG Adv. Op. No. 07-06 at 5 n.4.

- The requirement that charities "limit" the assistance they provide for high-cost or specialty drugs reflected a policy change by the OIG that it preferred fewer programs that would assist Medicare Part D beneficiaries in obtaining higher-cost drugs. *Compare* 2014 SAB, 79 Fed. Reg. at 31,122 (identifying as a recent

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question are . . . not false under the FCA"); *Hagood v. Sonoma Cty. Water Agency*, 81 F.3d 1465, 1477 (9th Cir. 1996) (granting summary judgment for FCA defendant where the proper allocation of project costs was "a disputed legal issue; that is not enough to support a reasonable inference that the allocation was *false* within the meaning of the False Claims Act"); *U.S. ex rel. Jamison v. McKesson Corp.*, 784 F. Supp. 2d 664, 677 (N.D. Miss. 2011) (differing interpretations of Medicare regulations were not grounds for FCA liability because "[i]f the regulations were thoroughly unclear, as a matter of law, the FCA's knowledge and falsity requirements have not been met"); *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 (5th Cir. 2003) (Jones, J., concurring) ("[W]here disputed legal issues arise from vague provisions or regulations, a contractor's decision to take advantage of a position can not result in his filing a 'knowingly' false claim.").

concern the fact that charities are "covering copayments only for expensive or specialty drugs"), *with* 2005 SAB, 70 Fed. Reg. at 70,623-70,624 (recognizing that patient assistance programs typically serve "patients with chronic illnesses and high drug costs"), *and* OIG Adv. Op. 06-10 at 2 (noting that CDF's patient assistance programs involve "costly medications").

- The requirement that charities not define funds by reference to "the stages of a particular disease, the type of drug treatment, and any other ways of narrowing the definition of widely recognized disease states" (2014 SAB, 79 Fed. Reg. at 31,121), fundamentally changed the way charities and industry operated. *Compare id.*, *with* OIG Adv. Op. 06-10 (approving CDF's operation of patient assistance program that provided cost-sharing assistance for specialty medications to patients who had been diagnosed with a disease state), *and* Not. of Mod. Of OIG Adv. Op. No. 06-10 at 2 (requiring CDF to agree to broadly define disease funds in order to maintain favorable advisory opinion).

Together, these new requirements changed the landscape of patient assistance programs to achieve the government's objectives of eliminating single drug/single donor funds and limiting, to the greatest extent possible, patient assistance with respect to high-cost and specialty drugs.

Moreover, in amending its guidance, the OIG acknowledged that "some charitable organizations with [patient assistance programs] have received favorable advisory opinions that may include features that are discouraged in this Supplemental Bulletin" – confirming inconsistencies between its earlier guidance and the 2014 guidance. 2014 SAB, 79 Fed. Reg. at 31,123. The OIG said: "[w]e are writing to all Independent Charity [patient assistance programs] that have received favorable opinions to explain how we intend to work with them to ensure that approved arrangements are consistent with our guidance. ***We anticipate that some opinions will need to be modified***." *Id.* (emphases added). Thereafter, the OIG modified six advisory opinions it previously had issued, requiring additional certifications by the affected charities that they would no longer engage in conduct similar to the alleged conduct by Questcor that the United States challenges in this case, including limiting assistance for high-cost or specialty drugs and maintaining a disease fund that provides copayment assistance for only one drug. *See* Not. of Mod. of OIG Adv. Op. Nos. 06-04, 06-10, 07-06, 07-11, 07-18, 11-05. In five of the

modified advisory opinions, including the modified opinion issued to CDF, the OIG expressly stated that its initial advisory opinions had "***approved certain features*** that ***we have since determined are problematic***." Not. of Mod. of OIG Adv. Op. No. 06-10 (emphasis added); *see also* Not. of Mod. of OIG Adv. Op. Nos. 06-04, 07-06, 07-11, 07-18.

The fact that the OIG saw fit to modify its prior advisory opinions to state that such conduct *could* run afoul of the AKS confirms that, at a minimum, prior to 2014, (1) the law on the subject was ambiguous, (2) Questcor's compliance with the prior guidance was objectively reasonable, and (3) Questcor was not "warned away" from its reasonable interpretation of the 2005 SAB and subsequent opinions confirming the industry-wide guidance set forth in it. Thus, even if the United States were to take the position that the OIG's current interpretation of the types of donations to *bona fide*, independent charities that violate the AKS is the right one, the United States cannot plausibly allege that Questcor's donations to CDF between 2010 and 2014 constituted knowing violations of the AKS or the FCA. (*See* Compl. ¶ 2 (defining the "relevant time period" as "2010 through 2014").) Put another way, although the government has the authority to alter its guidance and policies, and to clarify guidance it deems ambiguous, it cannot do so and then rely on its own changes to penalize entities that acted in conformance with that *prior* guidance. The government's changed position demonstrates that Questcor did not knowingly violate the AKS and that it did not knowingly cause false claims for Acthar to be submitted to the government. *See Pritsker*, 2009 WL 579380, at *17 (granting motion to dismiss FCA claims, noting changed and differing positions of government agencies on interpretation of regulations, and stating that "[t]he lack of clarity regarding the proper interpretation of the regulations indicates that no basis exists for imposing FCA liability on Defendants, who merely adopted a reasonable interpretation of regulatory requirements which favored their interests");

U.S. ex rel. Streck v. Allergan, Inc., 894 F. Supp. 2d 584, 596-97 (E.D. Pa. 2012) (granting motion to dismiss FCA claims for time period pre-dating statutory change to definition of calculation at issue: "[F]rom 2004 to at least January 2007, Plaintiff fails to plead sufficient facts that [Defendants'] interpretation of the statutory and regulatory scheme was unreasonable, let alone that [Defendants'] interpretation raised 'the "unjustifiably high risk" of violating the statute necessary for reckless liability.'" (citation omitted)), *aff'd*, 746 F. App'x 101 (3d Cir. 2018). For this additional reason, the United States' claims should be dismissed in their entirety.

III. PARAGRAPH 199 AND FOOTNOTE 5 OF THE COMPLAINT SHOULD BE STRICKEN.

Federal Rule of Civil Procedure 12(f) allows a court to strike from a pleading any "redundant, immaterial, impertinent, or scandalous matter." "The purpose of a motion to strike is to clean up the pleadings, streamline litigation, and avoid unnecessary forays into immaterial matters." *Guiliani v. Polysciences, Inc.*, 275 F. Supp. 3d 564, 572 (E.D. Pa. 2017) (citation omitted). Although relief under Rule 12(f) is generally disfavored, motions to strike are appropriate where, as here, the allegations "involve 'forays into immaterial matters' that 'may cause prejudice to one of the parties' or otherwise 'confuse the issues in the case.'" *Id.* at 574 (citation omitted).

The allegations in Paragraph 199 and footnote 5 fall squarely within the bounds of Rule 12(f) and should be stricken. In Paragraph 199, the United States alleges that it "regularly enforces the AKS and pursues FCA liability based on underlying violations of the AKS." (Compl. ¶ 199.) It then states, "[i]n particular" that "it has pursued matters against drug companies like [Questcor] for conduct like that alleged here" (*id.*), citing in a footnote its own press releases touting *recent* civil FCA settlements with *other* drug companies involving *other* drugs, *other* funds, and *other* charities (*id.* ¶ 199 n.5). Each press release states that "[t]he claims

resolved by the settlement are allegations only; there has been no determination of liability." (*See* Ex. S.)

The fact that the settlements exist has no bearing whatsoever on the purported sufficiency of the United States' allegations against Questcor. *See Loughrey v. Landon*, 381 F. Supp. 884, 888 (E.D. Pa. 1974) (striking paragraphs of the complaint alleging conduct of individuals who were not defendants in the case and stating: "While plaintiff argues vigorously contra, we fail to see the relevance of these allegations to the cause of action claimed by plaintiff. *They refer to persons other than the defendants* and to activities for which any cause of action has long since been barred by the statute of limitations. *Their presence may lead to unwarranted prejudicial inferences against the defendants*." (emphases added)). Nor do the settlements establish a regulatory scheme whereby Questcor was placed on notice that the alleged conduct was actionable. Each settlement occurred between December 2017 and April 2019 – years after the OIG changed its guidance in 2014.

Indeed, if considered, the fact that there have been such settlements serves only to underscore that the OIG's 2005 SAB and its subsequent advisory opinions through 2014 were at best ambiguous. If the OIG guidance had in fact prohibited such donations, the DOJ could have pursued *criminal* liability under the AKS rather than entering into *civil* settlements with the pharmaceutical manufacturers that donated to charitable foundations that provided copay assistance during the 2010 to 2014 time period.

In sum, the fact that other companies manufacturing other drugs elected to reach a compromise resolution with the government, rather than incur the cost of litigation and challenge the government's legal theory, is of no relevance to this action. For all these reasons, Paragraph 199 and the accompanying footnote should be stricken.

CONCLUSION

For the foregoing reasons, Questcor respectfully requests that this Court strike Paragraph 199 and footnote 5 from the Complaint and dismiss the Complaint in its entirety. Because the deficiencies in the United States' claims cannot be cured by amendment, Questcor respectfully requests that this action be dismissed with prejudice.

Respectfully submitted,

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